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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,807	01/22/2004	Stuart D. Shanler	132957.00101	4999

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EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,807	SHANLER ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/11/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 13-16* is/are pending in the application.

4a) Of the above claim(s) *4-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/11/08;7/20/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of January 11, 2008 made to the office action filed October 12, 2007. Claims 1-6 and 13-16 are pending. Claims 1 and 16 are amended and claims 4-6 are withdrawn based on Applicant's election of oxymetazoline as the adrenoreceptor agonist in the reply filed June 20, 2007. Claims 7-12 and 17-24 are canceled.

In light of the amendments to specification, the specification objection is withdrawn.

The Applicant's arguments of the following rejections were found persuasive, and thus withdrawn: 1) the 35 USC 102(e) rejection of claims 1-3, 7, 13, 14 and 16 as being anticipated by Dejovin et al.; 2) the 35 USC 103(a) rejection of claim 15 as being unpatentable over Dejovin et al. as applied to claims 1-3, 7, 13, 14 and 16 above in view of Yu et al. Particularly, the Examiner agrees that the provisional application 60/473,611, in which the Dejovin et al. reference claims priority, does not enable the compounds that were published in US 2004/0242588 A1. Thus, the effective filling date of the compounds filed in US 2004/0242588 A1 is May 25, 2004, which is after the filing date of the present application (January 22, 2004). Therefore the Dejovin is not a proper prior art reference.

Due to the withdrawal of all previous rejection, the new rejections are made below, which renders a new Non-Final rejection. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Information Disclosure Statement

During an interview filed June 13, 2008, the miscellaneous e-mail communication was given the date November 6, 2001.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Leal (email communication provided in IDS filed 1/11/08, November 6, 2001) as evidenced by Yu et al. (US 2004/0220259 A1).

Leal teaches that the Afrin (oxymetazoline; applicant's elected drug) solution effectively treats facial erythema.

In regards to treating rosacea, it is known in the art that treatment of erythema is an effective treatment of rosacea as evidenced by Yu et al. (see example 25).

In regards to claim 16, it is known in the art that rosacea is elicited by the factors disclosed in claim 16 (see specification, page 1, paragraph 3), and then dilation of the facial blood vessels occur (see specification, page 1, paragraph 1, lines 1-2). Therefore, regardless of how rosacea is elicited the method of Leal still treats rosacea.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(1) Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leal (email communication provided in IDS filed 1/11/08, November 6, 2001), im view of Yu. et al. (US 2004/0220259 A1).

The teachings of Leal are as applied to claims 1-3, 14 and 16 above.

Leal does not teach that oxymetazoline is co-administered with a therapeutically effective amount of another active agent listed in claim 13. Leal also does not teach that oxymetazoline is in the form of a soap or cleansing bar.

Yu et al. teach a method of topically treating dermatological disorders associated with dilated blood vessels, such as rosacea (see claims 1 and 4; page 1, paragraph 5, last 2 lines and paragraph 11, lines 1 and 12) comprising a topical agent such as oxymetazoline (see claims 2 and 26, line 22). Other ingredients may be incorporated in the compositions as long as the therapeutic properties of the polyhdroxy acids or lactones are not impeded, and in most cases, inclusion of more than one agent is desirable. Agents include anti-acne, anti-bacterial, anti-inflammatory, anti-histamine, anti-pruriginous, anesthetic, anti-viral, sunblock, sunscreen, and skin lightening agents (see page 4, paragraph 44, last 5 lines; paragraph 45 in its entirety). The composition can be formulated into gels, creams, lotions, solutions, sprays, emulsions, bars, shampoo(i.e. soaps), or those well known in the art (see page 3, paragraph 37).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Leal and to co-administer another effective amount of an active agent listed in claim 13, or to formulate the drug in a bar or soap because Yu et al. teaches that other ingredients may be incorporated in the compositions as long as the therapeutic properties of the polyhdroxy acids or lactones are not impeded, and in most cases, inclusion of more than one agent is desirable. Yu

et al. teaches that agents include anti-acne, anti-bacterial, anti-inflammatory, anti-histamine, anti-pruriginous, anesthetic, anti-viral, sunblock, sunscreen, and skin lightening agents (see page 4, paragraph 44, last 5 lines; paragraph 45 in its entirety). The composition can be formulated into gels, creams, lotions, solutions, sprays, emulsions, bars, shampoo(i.e. soaps), or those well known in the art (see page 3, paragraph 37). Thus to effectively treat rosacea, it is known and desirable to include other active agents. Additionally, it is well known to one skilled in the art to formulate compositions into bars or soaps.

(2) Claims 1-3 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu. et al. (US 2004/0220259 A1) in view of Applicant's admitted prior art (see specification, page 1, background of the invention, paragraphs 1 and 2; page 7, lines 16 and 17).

Yu et al. teach a method of topically treating dermatological disorders associated with dilated blood vessels, such as rosacea (see claims 1 and 4; page 1, paragraph 5, last 2 lines and paragraph 11, lines 1 and 12; addresses claim 1) comprising a topical agent such as oxymetazoline (see claims 2 and 26, line 22; addresses claims 1-3). Other ingredients may be incorporated in the compositions as long as the therapeutic properties of the polyhydroxy acids or lactones are not impeded, and in most cases, inclusion of more than one agent is desirable. Agents include anti-acne, anti-bacterial, anti-inflammatory, anti-histamine, anti-pruriginous, anesthetic, anti-viral, sunblock,

sunscreen, and skin lightening agents (see page 4, paragraph 44, last 5 lines; paragraph 45 in its entirety; addresses claim 13). The composition can be formulated into gels, creams, lotions, solutions, sprays, emulsions, bars, shampoo(i.e. soaps), or those well known in the art (see page 3, paragraph 37; addresses claims 14 and 15).

Yu et al. does not specifically teach a composition comprising oxymetazoline to treat rosacea, or wherein rosacea is elicited by the factors disclosed in claim 16.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Yu et al. and oxymetazoline to treat rosacea because the disorders treated by Yu et al. include rosacea because it is a condition associated with dilated blood vessels (see claims 1 and 4; page 1, paragraph 5, last 2 lines and paragraph 11, lines 1 and 12). Additionally oxymetazoline is a known vasoconstrictor (see specification page 7, lines 16 and 17), thus one would be motivated to use a vasoconstrictor in the composition of Yu et al. to reduce the dilated blood vessels that arise in rosacea.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Yu et al. and wherein rosacea is elicited by the factors disclosed in claim 16 because it is known in the art that rosacea is elicited by the factors disclosed in claim 16 (see specification, page 1, paragraph 3), and then dilation of the facial blood vessels occur (see specification, page 1, paragraph

1, lines 1-2). Therefore, regardless of how rosacea is elicited the method of Yu et al. still treats the rosacea itself by reducing the blood vessel dilation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. D. C./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617